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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Paper No. 04222011

Application Number: 09/095,323
Filing Date: June 10, 1998
Appellant(s): Laufer, Michael D.

Paul T. Parker
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed October 12, 2009.

(1) *Real .Party in Interest*

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) *Related Appeals and Interferences*

The following are the related appeals, interferences, and judicial proceedings known to the examiner which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal:

Appeal No. _____ (pending) on 10/810,276, continuation of 09/095,323.

(3) *Status of Claims*

The following is a list of claims that are rejected and pending in the application: 29-37, 50, 52-62.

(4) *Status of Amendments After Final*

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) *Summary of Claimed Subject Matter*

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) *Grounds of Rejection to be Reviewed on Appeal*

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

WITHDRAWN REJECTIONS

The following grounds of rejection are not presented for review on appeal because they have been withdrawn by the examiner, as rendered moot by appellant's amendment of May 13, 2009:

Claim 55 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, only with regard to the lack of positive antecedent basis for "the motor".

Claims 30, 32, 33, 35, 37, 52, 53, 56, 58, and 59 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Ivanyuta et al.

Claims 29, 30, 32-35, 37, 50, and 52-59 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,488,739. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patent anticipate the claims of the application.

Accordingly, instant application claims are not patentably distinct from the patent claims. Here, the patent claims require elements A, B, C, and D while instant application claim 1 only requires elements A, B, and C. Thus it is apparent that the more specific patent claims encompass the instant application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

Claims 33 and 50 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-51 of U.S. Patent Application No. 11/408,668. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application anticipate the claims of the instant application. Accordingly, instant application claims are not patentably distinct from the copending application claims. Here, the copending application claims require elements A, B, C, and D while instant application claims only requires elements A, B, and C. Thus it is apparent that the more specific copending application claims encompass the instant application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

(7) *Claims Appendix*

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Listing of Evidence Relied Upon

The following is a listing of the evidence (e.g. patents, publications, Official Notice, and admitted prior art) relied upon in the rejection of claims under appeal.

Number (Title)	Name	Date
4,754,065	Levenson	June 28, 1988
4,784,135	Blum et al	November 15, 1988
5,053,033	Clarke	October 1, 1991
5,422,362	Vincent	June 6, 1995
5,458,596	Lax et al	October 17, 1995
5,574,059	Regunathan	November 12, 1996
6,008,211	Robinson	December 28, 1999
WO 97/37715	Waksman et al	October 16, 1997
Mechanics of Airway Narrowing In Asthma	James et al	1989

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 29-37, 50, and 52-62 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the

claimed invention. The originally filed disclosure is silent on irradiating the tissue “irradiating the airway such that the ability of the smooth muscle to contract is reduced” further any particular parameters with regard to power, power density; energy; or energy density, for example, particularly those that would produce this particular effect are also not disclosed.

Claims 29-37, 50, and 52-62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are indefinite as the term “such that the ability of the smooth muscle to contract is reduced” lacks positive antecedent basis in the originally filed disclosure and thus the precise meaning of this term is unclear.

Claims 29, 32-34, 37, 50, and 56-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over James et al in combination with Clarke (US '033), Waksman et al, and Regunathan et al. James et al teach that the mechanisms involved in airway narrowing in asthma include hypertrophy and hyperplasia of smooth muscle (see page 242, column 1, second sentence) and that the thickening of smooth muscle is due to hyperplasia, rather than hypertrophy (see page 245, the sentence bridging columns 1 and 2) and that one of the results of the chronic inflammatory process present in the airway wall in patients with asthma is an inflammatory exudate containing mucus in the airway lumen (see 246, column 1, second full sentence). Regunathan et al teach that restenosis is a result of excessive proliferation (i.e. hyperplasia) and hypertrophy of smooth muscle cells, and that hyperplasia leads to thickening of the wall and narrowing of the lumen (see column 1, lines 17-26). Waksman et al teach the mechanism of smooth muscle cell hyperplasia (see page 3, line 23 to page 4, line 3), equivalence of treating

hyperplasia by doing smooth muscle damaging with laser radiation and nuclear radiation (see page 4, lines 4-14); and the equivalence of treating blood vessels (page 5, lines 13-25) and other lumens, including bronchi (page 5, lines 25-31), as well as treating the hyperplasia with a radioactive pellet (see page 6, lines 19-25). Clarke (US '033) teaches that restenosis can be treated by irradiation of the lumen wall with laser radiation (see column 2, lines 41-44) having wavelengths in the claimed ranges (see column 2, lines 63-67) to kill a portion of the smooth muscle cells to prevent the excessive replication and growth of smooth muscle cells (see column 3, lines 39-41). It would have been obvious to the artisan of ordinary skill use the method of Clarke (US '033) for treating asthma, since bronchial smooth muscle cells and vascular smooth muscle cells are equivalent, as taught by Waksman et al, and both asthma and restenosis involve hypertrophy of smooth muscle cells, as taught by James et al and Regunathan et al, and which hypertrophy results mainly from hyperproliferation, as taught by James et al, and to move the device while irradiating, since this would allow the treatment longer lesions, thus producing a method such as claimed.

Claims 30 and 35 are rejected under 35 USC 103 a, as being unpatentable over James et al in combination with Clarke (US '033), Waksman et al, and Regunathan et al as applied to claims 29, 32-34, 37, 50, and 56-59 and further in combination with Vincent et al. Vincent et al teach the desirability of treating proliferation of smooth muscle cells with irradiation with red light. It would have been obvious to the artisan of ordinary skill to employ irradiation with red light in the combined method of James et al, Clarke (US '033), and Regunathan et al, since this helps prevent smooth muscle cells from forming luminal occlusions, thus producing a method such as claimed.

Claim 36 is rejected under 35 USC 103 a, as being unpatentable over James et al in combination with Clarke (US '033), and Regunathan et al as applied to claims 29, 32-34, 37, 50, and 56-59 and further in combination with Waksman et al. Waksman et al teach the compatibility of radiation treatment and laser treatment for lumens including blood vessels and bronchi. It would have been obvious to the artisan of ordinary skill to employ irradiation with a radioactive pellet in the combined method of James et al, Clarke (US '033), and Regunathan et al, since this helps prevent smooth muscle cells from forming luminal occlusions, and is compatible with laser treatment, as taught by thus Waksman et al, thus producing a method such as claimed.

Claims 52-55 are rejected under 35 USC 103(a), as being unpatentable over James et al in combination with Clarke (US '033), Waksman et al, and Regunathan et al as applied to claims 29, 32-34, 37, 50, and 56-59 and further in combination with Lax et al. Lax et al teach the desirability of employing a painting motion (see column 10, lines 26-28) and the use of an endoscope when performing volume reduction procedures on tissue (see column 10, lines 44-46). It would have been obvious to the artisan of ordinary skill to employ a painting motion and endoscopic visualization in the combined method of James et al, Clarke (US '033), and Regunathan et al, since this would allow even disposition of energy and visualization of the treatment site, respectively, thus producing a method such as claimed.

Claims 60-62 are rejected under 35 USC 103 a, as being unpatentable over James et al in combination with Clarke (US '033), Waksman et al, and Regunathan et al as applied to claims 29, 32-34, 37, 50, and 56-59 and further in combination with Robinson et al and Levenson et al. Robinson et al teach the use of furocoumarin to prevent excess proliferation of smooth muscle

cells (see column 21, line 54 to column 22, line 45). Levenson et al teach that furocoumarins include psoralens (see column 2, lines 42-43). It would have been obvious to the artisan of ordinary skill to employ a psoralen in the combined method of James et al, Clarke (US '033), and Regunathan et al, since this helps to prevent smooth muscle cells from replicating, thus producing a method such as claimed.

Claims 29, 30, 32-35, 37, 50, and 52-59 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent Application No. 11/614,919. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application anticipate the claims of the instant application. Accordingly, instant application claims are not patentably distinct from the copending application claims. Here, the copending application claims require elements A, B, C, and D while instant application claims only requires elements A, B, and C. Thus it is apparent that the more specific copending application claims encompass the instant application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

Claims 29, 30, 32-35, 37, 50, and 52-59 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent Application No. 11/612,620. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application anticipate the claims of the instant application. Accordingly, instant application claims are not

patentably distinct from the copending application claims. Here, the copending application claims require elements A, B, C, and D while instant application claims only requires elements A, B, and C. Thus it is apparent that the more specific copending application claims encompass the instant application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

Claims 29, 30, 32-35, 37, 50, and 52-59 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 21-25 of U.S. Patent Application No. 11/618,533. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application anticipate the claims of the instant application. Accordingly, instant application claims are not patentably distinct from the copending application claims. Here, the copending application claims require elements A, B, C, and D while instant application claims only requires elements A, B, and C. Thus it is apparent that the more specific copending application claims encompass the instant application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

Claims 33 and 50 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-24 of U.S. Patent Application No. 11/609,242. Although the conflicting claims are not identical, they are not

patentably distinct from each other because the claims of the copending application anticipate the claims of the instant application. Accordingly, instant application claims are not patentably distinct from the copending application claims. Here, the copending application claims require elements A, B, C, and D while instant application claims only requires elements A, B, and C. Thus it is apparent that the more specific copending application claims encompass the instant application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

Claims 33 and 50 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent Application No. 11/608,606. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application anticipate the claims of the instant application. Accordingly, instant application claims are not patentably distinct from the copending application claims. Here, the copending application claims require elements A, B, C, and D while instant application claims only requires elements A, B, and C. Thus it is apparent that the more specific copending application claims encompass the instant application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

Claims 29, 30, 32-35, 37, 50, and 52-59 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent Application No. 11/617,512. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application anticipate the claims of the instant application. Accordingly, instant application claims are not patentably distinct from the copending application claims. Here, the copending application claims require elements A, B, C, and D while instant application claims only requires elements A, B, and C. Thus it is apparent that the more specific copending application claims encompass the instant application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

Claims 33 and 50 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-31 of U.S. Patent Application No. 11/562,925. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application anticipate the claims of the instant application. Accordingly, instant application claims are not patentably distinct from the copending application claims. Here, the copending application claims require elements A, B, C, and D while instant application claims only requires elements A, B, and C. Thus it is apparent that the more specific copending application claims encompass the instant application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower

invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

Claims 33 and 50 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent Application No. 11/425,345. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application anticipate the claims of the instant application. Accordingly, instant application claims are not patentably distinct from the copending application claims. Here, the copending application claims require elements A, B, C, and D while instant application claims only requires elements A, B, and C. Thus it is apparent that the more specific copending application claims encompass the instant application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

Claims 33 and 50 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent Application No. 11/421,444. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application anticipate the claims of the instant application. Accordingly, instant application claims are not patentably distinct from the copending application claims. Here, the copending application claims require elements A, B, C, and D while instant application claims only requires elements A, B, and C. Thus it is apparent that the more specific copending application claims encompass the instant

application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

Claims 33 and 50 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-40 of U.S. Patent Application No. 11/398,353. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application anticipate the claims of the instant application. Accordingly, instant application claims are not patentably distinct from the copending application claims. Here, the copending application claims require elements A, B, C, and D while instant application claims only requires elements A, B, and C. Thus it is apparent that the more specific copending application claims encompass the instant application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

Claims 33 and 50 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11-20 of U.S. Patent Application No. 11/420,442. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application anticipate the claims of the instant application. Accordingly, instant application claims are not patentably distinct from the copending application claims. Here, the copending application claims require

elements A, B, C, and D while instant application claims only requires elements A, B, and C. Thus it is apparent that the more specific copending application claims encompass the instant application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

Claims 33 and 50 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 26 and 27 of U.S. Patent Application No. 11/361,564. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application anticipate the claims of the instant application. Accordingly, instant application claims are not patentably distinct from the copending application claims. Here, the copending application claims require elements A, B, C, and D while instant application claims only requires elements A, B, and C. Thus it is apparent that the more specific copending application claims encompass the instant application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

Claims 33 and 50 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 15-29 and 32 of U.S. Patent Application No. 11/117,905. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application

anticipate the claims of the instant application. Accordingly, instant application claims are not patentably distinct from the copending application claims. Here, the copending application claims require elements A, B, C, and D while instant application claims only requires elements A, B, and C. Thus it is apparent that the more specific copending application claims encompass the instant application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

Claims 29, 30, 32-35, 37, 50, and 52-59 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent Application No. 10/810,276. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application anticipate the claims of the instant application. Accordingly, instant application claims are not patentably distinct from the copending application claims. Here, the copending application claims require elements A, B, C, and D while instant application claims only requires elements A, B, and C. Thus it is apparent that the more specific copending application claims encompass the instant application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

Claims 50, 52, and 53 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13-28 of copending

Application No. 11/617,512. It would have been obvious to the artisan of ordinary skill to use the device for its intended purpose.

Claims 50 and 56 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of copending Application No. 11/562,910. It would have been obvious to the artisan of ordinary skill to use the device for its intended purpose.

Claims 33 and 50 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 81-100 of copending Application No. 11/614,914. It would have been obvious to the artisan of ordinary skill to use the device for its intended purpose.

Claims 29, 30, 32-35, 37, 50, and 52-59 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of copending Application No. 11/562,925. It would have been obvious to the artisan of ordinary skill to use the device for its intended purpose.

Claims 29, 30, 32-35, 37, 50, and 52-59 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12-17 of copending Application No. 11/612,620. It would have been obvious to the artisan of ordinary skill to use the device for its intended purpose.

Claims 29, 30, 32-35, 37, 50, and 52-59 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of copending Application No. 11/618,533. It would have been obvious to the artisan of ordinary skill to use the device for its intended purpose.

Claims 33 and 50 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12-36 of copending Application No. 11/608,606. It would have been obvious to the artisan of ordinary skill to use the device for its intended purpose.

Claims 33 and 50 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 of copending Application No. 11/361,564. It would have been obvious to the artisan of ordinary skill to locate the treatment site prior to treatment.

Claims 33 and 50 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 81-101 of copending Application No. 11/534,621. It would have been obvious to the artisan of ordinary skill to use the device for its intended purpose.

(10) Response to Argument

A) Rejection Of Claims 29-37, 50, And 52-62 As Failing to Comply With The Written Description Requirement Under 35 USC 112 1st Paragraph

1) Legal Standard For Written Description

The examiner agrees with the stated legal standard for the written description stated in the Brief.

2) The Examiner's Position

The examiner essentially agrees with appellant's stated basis for the rejection under 35 U.S.C. 112, first paragraph, the differences will be elucidated in section 3), below.

3) Appellant's Position

With regard to the rejection based on the written description requirement, appellant argues that the examiner based this rejection on language that was deleted from the claim by the amendment submitted July 22, 2008, wherein the term "smooth muscle" was replaced with -- airway -- (see the instant Brief, the first two sentences of the second full paragraph on page 12). Before addressing this argument, the examiner must respectfully note that in the claims submitted on May 13, 2009, which amendment was entered (see the Advisory Action mailed June 18, 2010) and in the copy of the appealed claims attached to the instant Brief, claim 50 now recites "causes debulking of smooth muscle tissue...". Thus this argument must fail. However, assuming such a recitation was not explicitly claimed therein, in order to determine the scope of the claims, one must look to the originally filed disclosure. Doing so, one finds that the root "contract-" and words deriving therefrom appear in the originally filed disclosure a total of six times: "Asthma is a disease which involves heightened reactivity of the tracheobronchial tree to numerous stimuli causing **contraction of smooth muscle** surrounding the airway of the lungs" (see the originally filed disclosure, page 1, lines 9-11, no Pre-Grant Publication exists for this application, emphasis added); "In a healthy patient, the **smooth muscle surrounding the airway**

contracts..." (see the originally filed disclosure, page 1, lines 14-15, emphasis added); "With...hyperreactive airways a very small amount of pollen allergen or other material in the air will stimulate a large amount of **smooth muscle contraction...**" (see the originally filed disclosure, page 1, lines 17-19, emphasis added); "repeated **contraction of the smooth muscle** exercises the muscle..." (see the originally filed disclosure, page 1, line 20, emphasis added); "The airway is surrounded by **smooth muscle tissue 52 which is capable of contracting** to shrink the diameter of the airway" (see the originally filed disclosure, page 6, lines 3-4, emphasis added); and "elimination of the **smooth muscle tissue prevents the hyperreactive airways of an asthma patient from contracting...**" (see the originally filed disclosure, page 11, lines 7-8, emphasis added). Thus as clearly set forth in the disclosure, the contraction of the airway is due to the contraction of the smooth muscle, thus merely rewording the claim to recite that the airway is prevented from contracting, still requires the smooth muscle to be prevented from contracting. Thus the rejection, which is based on the originally filed disclosure being "silent on irradiating the tissue "such that the ability of the smooth muscle to contract is reduced" further any particular parameters with regard to power, power density; energy; or energy density, for example, particularly those that would produce this particular effect are also not disclosed" (see the office action mailed January 16, 2009, the paragraph spanning pages 8 and 9 thereof). As appellant has merely argued the semantic construction of the claim, rather than the limitations it states, and has further in no way addressed the lack of disclosure with respect to the particulars of the parameters discussed in the rejection, which particulars are entirely absent from the originally filed disclosure, these arguments are not convincing. It is the examiner's view that this rejection is proper and should be upheld.

B) Rejection Of Claims 29-37, 50, And 52-62 As Indefinite Under 35 USC 112

2nd Paragraph

With regard to the rejection under 35 U.S.C. 112, second paragraph, appellant's arguments are essentially the same as those set forth above with respect to the rejection under 35 U.S.C. 112, first paragraph. The examiner's position is likewise essentially the same. Since the contraction of the airway involves the contraction of smooth muscle, and since no particular parameters, as discussed with regards to the rejection under 35 U.S.C. 112, first paragraph, are set forth which would produce this effect, that which the claim encompasses in terms of the "irradiating..." step is unclear. Thus, in order to determine that which is encompassed by the claim, one of ordinary skill in the art would be forced to engage in extensive trial and error to determine what the metes and bounds of the claim are, and would be unable to do so, until actually having infringed the claim (by determining the power levels, etc, via actually applying them to an airway and producing the claimed results). Thus it is the examiners view that the claims are indefinite and the rejection is proper and should be upheld.

C) Rejection Of Claims 29, 32-34, 37, 50, And 56-59 As Obvious Under 35

U.S.C. 103(a)

1) Legal Standard For Obviousness

The examiner agrees with the stated legal standard for the obviousness stated in the Brief.

2) The Examiner's Position

After reviewing the examiner's basis for the rejection, appellant then summarizes the examiner's treatment of the Laufer Declaration.

3) Appellant's Position

D) Claims 29, 32-34, 37, 50, And 56-59 Are Obvious Over James et al., Clarke, Waksman et al, and Regunathan et al

a. Laufer Declaration

Now appellant discusses the examiner's treatment of the Laufer Declaration, asserting that "the Laufer Declaration should be given significant patentable weight even though Dr. Laufer is an interested party because it is supported by extrinsic evidence and Dr. Laufer has been a person of ordinary skill in the art since before 1998" (see the instant Brief, the second sentence of the first full paragraph on page 18). However, as set forth in the rejection mailed January 16, 2009, "while not to be lightly disregarded, is seldom acceptable as conclusive of factual matter stated therein, in general such affidavits are accorded the status of expression of opinion by expert in the art...yet, law demands close scrutiny of such affidavits, particularly

where affiant is not disinterested party” (see *In re Guild* 98 USPQ 68, 69 (CCPA))’ (see the rejection mailed January 16, 2009, the sixth full sentence on page 5) , further MPEP 716(c)(III) makes it clear that “In assessing the probative value of an expert opinion, the examiner must consider the nature of the matter sought to be established, the strength of any opposing evidence, the interest of the expert in the outcome of the case, and the presence or absence of factual support for the expert’s opinion. *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 227 USPQ 657 (Fed. Cir. 1985), cert. denied, 475 U.S. 1017 (1986).” Clearly and undeniably Declarant is not a disinterested party. Not only does Declarant have a financial interest in the instant application, but as Declarant is also the sole inventor, there is a personal interest in the instant application as well. Thus, while Declarant is clearly skilled in the art, and was so at the time of the invention, the interest of Declarant in the outcome of the case cannot be discounted when evaluating the opinions set forth in the Declaration. Next appellant asserts that the Laufer Declaration should be significant weight because it is drawn to the claimed subject matter. The examiner disagrees with appellant’s assessment of the scope of the subject matter with regards to the Declaration, as will be explained more fully below. Similarly, appellant asserts that there is sufficient nexus between “merits of the claimed invention and the evidence of secondary considerations” (see the instant Brief, the last sentence of the second full paragraph on page 19). Again, the examiner disagrees, for reasons that will be more fully enumerated below.

Continuing, appellant asserts that the Laufer Declaration “provides extrinsic evidence that teaches away from decreasing airway smooth muscle thickness” (see the instant Brief, the fourth sentence of the paragraph bridging pages 18 and 19). Next appellant notes that the

examiner stated that the teaching of James et al of reversing the chronic inflammatory process would require reversing smooth muscle hypertrophy. The examiner maintains that, while the wording in the office action may have been too strong, and that while not specifically requiring the reversal of smooth muscle hypertrophy, one of ordinary skill in the art would undeniably understand from the teachings of James et al that reversal of smooth muscle hypertrophy and hyperplasia would relieve asthmatic symptoms, and thus would be a legitimate and desirable treatment therefor. Also appellant asserts that the Laufer Declaration “establishes that James does not teach debulking or otherwise affecting smooth muscle tissue to reverse the inflammatory process associated with asthma and that the United States Food and Drug Administration (USFDA) was so skeptical of debulking airway smooth muscle that it denied approval of doing so until 2005” (see the instant Brief, the first full sentence on page 19). It is the examiner’s view that it is not required that James et al “teach debulking or otherwise affecting smooth muscle tissue to reverse the inflammatory process associated with asthma” per se, to support a finding of obviousness, all that is required is that the combination of references as a whole suggest to one of ordinary skill in the art at the time the invention was made to debulking or otherwise affecting smooth muscle tissue. Since one of ordinary skill in the art is well aware that the treatment of asthma is to provide a more patent airway, and since the airway is rendered less patent by the hyperproliferation of smooth muscle cells, as shown by James et al, one of ordinary skill in the art would readily glean from these teachings that changing the smooth muscle to have reduced prominence would provide a treatment for asthma. For example the Laufer Declaration asserts that “James et al concludes that changes produced by chronic inflammatory can lead to excessive airway narrowing without excessive smooth muscle

contraction such that the treatment of asthma should focus on (a) reversing the inflammatory changes in the airway wall and (b) relaxation of the airway smooth muscle. (James at p. 246, col. 1.)” (see Laufer Declaration, paragraph 7, last sentence), would clearly suggest to one of ordinary skill in the art that a viable treatment for asthma could include producing a change in the smooth muscle to debulk the muscle and thereby open the airway.

Continuing, appellant asserts that the examiner “erred in asserting that the Laufer Declaration is not per se drawn to the claimed invention” (see the instant Brief, the first sentence of paragraph bridging pages 19 and 20), and referring to the last sentence of paragraph 8 of the Laufer Declaration, which states that at the time of the invention, one of ordinary skill in the art “would have understood that airway smooth muscle had a functional purpose and that airway smooth muscle should not be killed” asserts that “[N]othing in the last sentence of paragraph 8 of the Laufer Declaration describes a situation that is limited to killing all of the airway smooth muscle cells” (see the instant Brief, the next to last full sentence on page 19). And appellant goes on to state that the Laufer Declaration “establishes, *inter alia*, that a person skilled in the art at the time of the invention would have understood that airway smooth muscle cells should not be killed to the extent that the lack of larger airway smooth muscle tone could impede the functional purpose that airway smooth muscle was thought to perform in normal lung function at the time of the invention” (see the instant Brief, the last full sentence on page 19). The examiner firstly notes that this argument appears at odds with the argument regarding the rejections based on the written description and the indefiniteness of the claims, which apparently purport that the removal of the recitation of smooth muscle cells from the claims removes this limitation therefrom, which would provide another basis for concluding that the Laufer Declaration

providing arguments drawn to an invention narrower than that encompassed by the claims. This aside, however, and presuming, as appellant is now apparently arguing, that the claimed method is restricted to acting on at least smooth muscle tissue, the examiner must respectfully disagree with appellant's assessment of the relevancy to the claimed invention. Nowhere in the claims at bar is there a requirement that any of the affected cells be "killed" - it is merely claimed, in claim 50, that the treatment cause "debulking of smooth muscle tissue of the asthmatic lung, and prevents the lung tissue from replicating" (no limitation as to the type of cells affected is required by claim 50). Similarly, nowhere in the claims at bar is there any restriction on the amount of cells (e.g. an amount large enough to cause a "lack of larger airway smooth muscle tone" or to "impede the functional purpose that airway smooth muscle was thought to perform") that are so changed. Further, there is no restriction on the location of the smooth muscle cells, other than they be situated in "an airway". The originally filed disclosure provides no special definition for the term "airway" and thus this term is give its ordinary and customary meaning in the art (see MPEP 2111.01(III)), which includes any of the passages in the body through which air travels to reach the alveoli. So the claims are not restricted to smooth muscle in a "larger airway" as argued. For at least these reasons, the statements regarding what one of ordinary skill in the art would consider appropriate for treatment of smooth muscle in an airway are not commensurate in scope with the claimed invention.

Turning to the heavily redacted exhibit denying approval for a clinical trial of a device applied for by the assignee of the instant application, appellant asserts that paragraph 9 of the Laufer Declaration "establishes that experts were skeptical about decreasing airway smooth muscle tissue at the time of the invention" (see the instant Brief, the first sentence of the first full

paragraph on pages 21). However, it is the examiner's view that the exhibit provided with the Laufer Declaration is also not commensurate with the scope of the claimed invention. Firstly, the text from the letter from the USFDA reproduced in the instant Brief refers to "ablation" rather than "debulking" or preventing "replicating". Secondly, the text makes reference to "smaller airway bronchospasm" and "larger airway smooth muscle tone" implying that both types of airway are treated. However the claims do not require that both sizes of airway be treated, nor do they require that all of a given size of airway be treated. The instant claims encompass a situation where one centimeter of one airway is treated to reduce bronchoconstriction therein. The instant claims also encompass a situation where all the or some of the airways are treated to kill or ablate a fraction, for example one half, one quarter, or one tenth of the smooth muscle cell thickness uniformly along the length of the treated airways thereby opening the airway (or "debulking the smooth muscle") while still leaving a majority of the smooth muscle in place to provide the physiological function attributed thereto at the time of the invention. Thus, even if the treatment did involve the killing or ablation of smooth muscle cells (which killing or ablation, the claims at bar do not require), doing so in such a limited location (e.g. one centimeter of length in one airway) or to a limited depth uniformly (e.g. one quarter of the thickness) would not imperil the individual as described in the response from the USFDA. Additionally, as already set forth in the rejection of January 21, 2009, there is no indication of the manner in which the device is used or the energy applied. Thus, it is simply not clear what methods are involved, however it is clear that the treatment is limited to ablation, rather than "changes" in cells. Thus, for at least these reasons, the evidence is not commensurate with the scope of the claims.

Regarding paragraph 10 of the Laufer Declaration, appellant asserts that this “establishes that James teaches the increase in airway wall thickness associated with asthma is not confined to the airway smooth muscle” (see the instant Brief, the first sentence of the first full paragraph on page 22), and that “James does not teach any specific mechanism to reverse the inflammatory progression in the airway wall” (see the instant Brief, the second sentence of the first full paragraph on page 22). However, James et al do teach that the area taken up by smooth muscle is at a minimum one third of the area of the larger airway walls in asthmatics, as can be seen from the disclosure in the two full paragraphs in column 3 of page 243, and Table 1 of James et al, at the top of page 244 - internal perimeter >2 mm – total area = $0.156 + 0.135 + 0.152 = 0.443$, with smooth muscle accounting for $0.156/0.443 = 35.2\%$; internal perimeter <10 mm – total area = $0.46 + 0.73 + 0.67 = 0.186$, with smooth muscle accounting for $0.67/0.186 = 35.9\%$; internal perimeter >10 mm – total area = $0.88 + 1.35 + 1.57 = 0.443$, with smooth muscle accounting for $1.57/3.80 = 41.3\%$. This clearly shows that, while not entirely responsible for the totality of the airway diameter reduction, hyperplasia of smooth muscle is a significant component responsible for airway reduction. These teachings are directed to one of ordinary skill in the art, who would readily recognize that ameliorating these conditions would improve asthma. Further it is noted that James et al is not the only reference applied to the claims. The claims are rejected as obvious over the *combination* of James et al, Clarke, Waksman et al, and Regunathan et al, and it is these latter references, particularly Clarke and Waksman et al that teach methods by which smooth muscle hyperplasia is controlled. Thus it is not necessary for James et al to provide this teaching as well. The fact that James teaches that factors other than smooth muscle hyperplasia play a role in asthma, does not remove from James et al the teaching

that smooth muscle hyperplasia is involved to a significant degree in airway constriction, and given that the smooth muscle need not be completely eradicated, but merely reduced (see e.g. Clarke column 3, lines 39-41: “carrying the UV radiation to kill **a portion** of the cells in the vicinity of the ablation site which would otherwise proliferate” (emphasis added)). The showings of paragraphs 7-9 of the Laufer Declaration merely demonstrate that one of ordinary skill in the art would not eradicate all smooth muscle cells from all the airways. However, this procedure is far narrower than the procedure covered by the instant claims or taught by the applied references.

Proceeding to paragraph 14 of the Laufer Declaration, appellant states that restenosis in vascular structures is hyperplasia, as opposed to hypertrophy. Also asserted is that hyperplasia is the excessive proliferation of cells, while hypertrophy is the increase in the size of cells without necessarily increasing the number of cells. And appellant concedes that the examiner’s definition of hyperplasia is accurate, but asserts that the examiner read the “SEE ALSO hypertrophy” as implying that hyperplasia and hypertrophy are synonymous. This is inaccurate. The examiner clearly stated that “hypertrophy can include hyperplasia” (see the first full sentence on page 7 of the rejection mailed January 16, 2009), not that the two words meant the same thing. This is borne out by the definition of hypertrophy set forth in the brief (also from Stedman’s Medical Dictionary, 26th Edition) “general increase in bulk or a part of organ, not due to tumor formation. Use of the term **may** be restricted to denote greater bulk through increase in size but not in number of cells or other individual tissue elements.” (see the instant Brief, the first sentence of the first full paragraph on page 17, emphasis added) denotes that this is not the only definition thereof. Then appellant goes on to conclude that “Stedman’s accordingly

supports defining hyperplasia and hypertrophy as two distinct mechanisms” (see the instant Brief, the fourth sentence on page 23). The examiner must respectfully disagree. As set forth above and in the rejection mailed January 16, 2009, the two terms are clearly overlapping, with hyperplasia describing a subset of the conditions that are covered by hypertrophy. This is further supported by the definition of hyperplasia set forth in Stedman's Medical Dictionary, 26th Edition which also includes: “SYN numerical hypertrophy, quantitative hypertrophy” thus while the terms hypertrophy and hyperplasia are not identical, the meaning ascribed to the term “hyperplasia” is encompassed by the definition of the term “hypertrophy”. As applicant has provided no special definition of the term “hypertrophy” in the originally filed disclosure, this term must be read as conveying its normal and customary meaning in the art (see MPEP 2111.01(III)). The term must also be given its broadest reasonable interpretation in light of the supporting disclosure (see MPEP 2106(II)(C) and *In re Morris* 127 F.3d 1028, 1054-1055, 44 USPQ2d 1023, 1027-1028 (Fed Cir 1997)), and thus can be read to include hyperplasia.

Concerning paragraph 15 of the Laufer Declaration, appellant states that “the Laufer Declaration correctly states that neither Regunathan nor Clarke teaches debulking tissue or otherwise removing uninjured smooth muscle tissue that existed before an injury” (see the instant Brief, the first sentence of the first full paragraph on page 23). It is noted that the “injury” status of the smooth muscle treated is nowhere mentioned either in the instant claims, or the originally filed disclosure. Thus here too, Declarant is offering assertions with regard to a method which is narrower than the scope of the claims at bar. Continuing, appellant asserts that “[B]oth of these references are clear that the restenosis (or narrowing of the lumen) treated by their methods is caused by hyper-proliferation” (see the instant Brief, the second sentence of the

first full paragraph on page 23, parenthetical comment added). The examiner respectfully notes that Regunathan et al expressly states that “[A] major pathogenic mechanism contributing to vascular pathology in atherosclerosis, hypertension resulting from renal artery stenosis and other causes, restenosis of coronary and other arteries after coronary angioplasty, insertion of vascular stents or due to non-angioplasty injury to blood vessels and proliferative diabetic retinopathy, is vascular **hyperplasia, i.e., the excessive proliferation and hypertrophy** of vascular smooth muscle cells (see Regunathan et al, column 1, lines 17-24, emphasis added). Thus clearly, one of ordinary skill in the art recognizes that hyperplasia, while a subset of hypertrophy, is encompassed thereby.

In summary, while appellant has noted some statements of Declarant, there are several that are not correct, many of these statements are true as far as they go, but discount or disregard other facts set forth in the reference discussed or in the other references applied to the claims, and disregard the basic knowledge of one of ordinary skill in the art, or the ordinary creativity with which one of ordinary skill in the art is credited by the ruling in *KSR v Teleflex*, as set forth above. The fact that Declarant is not a disinterested party coupled with the deficiencies in the analysis of the references applied to the claims and the casting of the invention in terms narrower than the scope of the claims at bar, outweigh the assertions set forth therein, and the assertions are accordingly not convincing, as set forth in MPEP 716(c)(III) and *In re Guild*, discussed above.

b. Meaning of the Cited References

James et al teach that mechanisms involved in airway narrowing in asthma include hypertrophy and hyperplasia of smooth muscle (see page 242, column 1, second sentence) and that the thickening of smooth muscle is due to hyperplasia, rather than hypertrophy (see page 245, the sentence bridging columns 1 and 2) and that one of the results of the chronic inflammatory process present in the airway wall in patients with asthma is an inflammatory exudate containing mucus in the airway lumen (see 246, column 1, second full sentence). Thus airway narrowing is caused by both smooth muscle hyperplasia and inflammatory processes, which involve excessive mucus production. Thus one of ordinary skill in the art would realize that treating either of these conditions would mitigate asthmatic symptoms.

Regunathan et al teach that vascular hyperplasia, i.e., the excessive proliferation and hypertrophy of vascular smooth muscle cells, is a major pathogenic mechanism which contributes to vascular pathology, including restenosis. In the actual passage from Regunathan et al, it is stated that the major pathogenic mechanism “is vascular hyperplasia, i.e., the excessive proliferation and hypertrophy of vascular smooth muscle cells.”. Note that the entire phrase “excessive proliferation and hypertrophy” is set off by a comma, meaning that the entire phrase is a modifier to the term “hyperplasia”. While the method of Regunathan et al for controlling the proliferation does not specifically relate to the claimed invention, the cited passage therein serves to demonstrate that one of ordinary skill in the art understands that “hyperplasia” can be termed “hypertrophy” even though they are not synonymous.

Clarke teaches smooth muscle cell hyperplasia contributes significantly to restenosis and that such hyperproliferation can be mitigated by the application of UV radiation of the claimed range to the smooth muscle cells to kill not all, but merely a portion of these cells (see column 2,

lines 41-44 and lines 63-67) to “kill a portion of the cells in the vicinity of the ablation site which would otherwise proliferate” (see column 3, lines 39-41). Thus teaching one of ordinary skill in the art that only some of the cells, and not all of them need be treated with light in the 240 nm to 280 nm wavelength range to effect the desired result.

Waksman et al teach the mechanism of smooth muscle cell hyperplasia (see page 3, line 23 to page 4, line 3), equivalence of treating hyperplasia by doing smooth muscle damaging with laser radiation and nuclear radiation (see page 4, lines 4-14); and the equivalence of treating blood vessels (page 5, lines 13-25) and other lumens, including bronchi (page 5, lines 25-31). Thus one of ordinary skill in the art would understand, from the teachings of Waksman et al, that hyperproliferation of smooth muscle cells is responsible for lumen narrowing; that it can be treated by radiation and by laser irradiation; and that treatments employed for smooth muscle cell hyperplasia can be employed in bodily lumens other than blood vessels, specifically the bronchi. It is noted that appellant asserts that “in all of the applications disclosed by Waksman, his invention is directed toward inhibiting the proliferation of additional cells at an area that has been injured during an earlier procedure” (see the instant Brief, the sentence bridging pages 25 and 26). This statement is inaccurate. While Waksman et al do mention the use of the method on some injured areas, other non-injured areas are also taught as being so treated: “present invention is particularly applicable, but not limited, to the treatment of coronary arteries that have been **or will be** subjected to PTCA or other artery opening procedures” (page 5, lines 13-16, emphasis added); “bypass grafts may be treated either before or after they are implanted (page 5 lines 23-24); “present invention is also useful in areas of the body where endoscopic procedures are performed” (page 5, lines 31-33, note there is no requirement that the endoscopic

procedures be surgical, as opposed to diagnostic). Separate and apart from this, it is well understood that “A person of ordinary skill is also a person of ordinary creativity, not an automaton.” *KSR International Co. v Teleflex Inc.* 82 USPQ2d 1385, 1397 (Supreme Court, 2007), thus, for example, when performing a diagnostic endoscopic procedure, if an area of hyperplasia of smooth muscle cells were encountered, one of ordinary skill in the art would readily understand that the area could be treated by e.g. the method of Waksman et al (or Clarke, for that matter), rather than leaving a pathological area untreated, or having to first damage the area, then treat it.

c. Regarding Claim 50, One Of Ordinary Skill In The Art Using The Combined Teachings Of James Et Al, Clarke, Regunatan Et Al And Waksman Et Al Would Have Employed Ultraviolet Radiation In The 240 nm to 280 nm Range To Treat Smooth Muscle Hyperplasia.

First appellant asserts that the rejection is improper because the examiner “incorrectly concludes that James’ teachings require the reversal of airway smooth muscle hypertrophy” (see the instant Brief, the first sentence of the paragraph bridging pages 26 and 27). The examiner notes that while James et al may not require the reversal of smooth muscle hypertrophy, the teachings of James et al, do include that the increase in smooth muscle volume is mainly due to hyperplasia, as taught by James et al in the sentence bridging columns 1 and 2 of page 245: “Dunnill and colleagues (8) reported an increase in smooth muscle in the major bronchi of asthmatic subjects, and Heard and Hossain (9) showed that this was due to hyperplasia rather

than hypertrophy of the muscle". Since 35 U.S.C. 103(a) and the ruling in KSR require that the teachings be analyzed as viewed by one of ordinary skill in the art, these teachings would suggest that the symptoms of asthma would be mitigated by reversing the smooth muscle hyperplasia. Next appellant discusses other aspects of James et al, regarding the inflammatory process, but these have little bearing on the combination as applied to claim 50. Then appellant notes that James et al "does not teach any mechanism to debulk airway smooth muscle" (see the instant Brief, the last sentence on page 26). It is the examiner's view that this is precisely why one of ordinary skill in the art would look to areas concerned with reducing smooth muscle hyperplasia to determine such mechanisms.

Continuing appellant asserts that the examiner "fails to establish that a person skilled in the art at the time of the invention would have selected decreasing airway smooth muscle thickness to treat asthma" (see the instant Brief, the first sentence of the first full paragraph on page 27), asserting that the examiner relies only on James et al for this. The examiner must respectfully disagree. The examiner relies on the teachings of James et al in combination with the other references in the combination applied to the claims and the knowledge of one of ordinary skill in the art, that to mitigate the symptoms of a condition, the physiological response that causes the condition must be reversed, as any medical professional would be well aware. Then appellant asserts that one of ordinary skill in the art at the time of the invention thought that airway smooth muscle performed an important function, citing paragraphs 8 and 9 of the Laufer Declaration; the USFDA letter dated February 16, 2001; and the Macklin article discussed in paragraph 8 of the Laufer Declaration, and thus would not have reduced airway smooth muscle mass as a treatment for asthma. However, as stated above, these assertions refer to total

eradication of the airway smooth muscle, and thus are not commensurate with the scope of the claims, which encompass, among other things, the removal of only a portion (as taught by Clarke) e.g. one tenth of the excess smooth muscle cells, due to the hyperplasia thereof, hyperplasia being the main cause of the narrowing, as taught by James et al. Ablation of one tenth, one quarter, or one half of the thickness of the smooth muscle produced by the hyperplasia resulting in asthma, would still leave a substantial percentage of smooth muscle tone, since, as stated in the originally filed disclosure, normal lungs have smooth muscle thickness of 0.01 mm, while asthmatic lungs have a smooth muscle thickness of 2-3 mm, or 200 to 300 times the thickness of smooth muscle in normal lungs (see lines 3-6 on page 2 of the originally filed disclosure). Thus, as stated above, these assertions, coupled with the fact that Declarant is an interested party, cannot be afforded great weight and do not overcome the examiner's *prima facie* showing of obviousness.

Next appellant asserts that the examiner "erred by completely dismissing the statement from the USFDA" (see the instant Brief, the last sentence on page 27). However, as just stated, and as enumerated more fully with regard to paragraph 9 of the Laufer Declaration in section (I)(a) above, the letter from the USFDA indicates, to the extent that the examiner can determine from the heavily redacted version supplied by appellant, that the procedure being reviewed entailed total ablation of the smooth muscle throughout the entire airway system, rather than any partial ablation, either in thickness or in extent of the airway system, these assertions of the positions of one of ordinary skill in the art at the time of the invention are much narrower than the methods encompassed by claims at bar.

Concerning the teachings of Clarke, appellant states that the examiner “fails to establish that Clarke’s process for preventing excessive growth of new cells in response to vascular injury would be used to debulk uninjured, hypertrophied airway cells” (see the instant Brief, the first sentence of the first full paragraph on page 28). The examiner must respectfully disagree. This is established by the teachings of Waksman et al, regarding the use of smooth muscle debulking in vasculature and bronchi, set forth above in section (I)(b) with respect to the teachings of Waksman et al. Continuing appellant asserts that the examiner takes the position “that hypertrophy can include hyperplasia and that James uses the terms hypertrophy and hyperplasia interchangeably” (see the instant Brief, the second sentence of the first full paragraph on page 28). The examiner reiterates that hypertrophy can indeed include hyperplasia, as set forth above in section (I)(b) with regard to the discussion of the teachings of Regunathan et al. However, the examiner has never maintained that these terms are interchangeable. Further, the examiner notes that James et al do not use the terms hypertrophy and hyperplasia interchangeably, but do expressly state that airway smooth muscle thickening is due to hyperplasia, rather than hypertrophy, as set forth above in section (I)(b) with regard to the teachings of James et al at page 245. Turning to Regunathan et al, appellant chooses to focus on the treatment of Regunathan et al, rather than the teaching upon which the examiner relies. However, it is the examiner’s view that one of ordinary skill in the art would not seek to use a **vascular** smooth muscle anti-proliferative pharmacological agent to remedy a condition in the bronchi. But one of ordinary skill in the art would note the modifier of hyperplasia, which includes hypertrophy. Continuing discussing Regunathan et al, appellant asserts that “Regunathan does not teach reducing the size of existing, uninjured smooth muscle cells” (see the instant Brief, the last

sentence on page 28). The examiner has never put forth this proposition. Nor do the claims at bar included any limitation regarding the reduction of size of any cells, or that the cells acted on be uninjured.

Returning to James et al, appellant notes the passage at 245 cited above. In an attempt to dismiss the teaching, appellant acknowledges it, but argues “James did not confirm that the cause was hyperplasia” (see the instant Brief, the next to the last full sentence on page 31). However, neither does James et al assert that this is not the case. A fair reading of James et al can only lead to the conclusion that James et al do not dispute the findings of Heard and Hossain. However, appellant attempts to contradict this by asserting “that James consistently used only hypertrophy” (see the instant Brief, the sentence bridging pages 31 and 32). However, this is not true. In the second sentence of the James et al article, James notes that “studies have shown...smooth muscle hypertrophy and hyperplasia (9) in the bronchial walls of asthmatic patients”. It is curious that James et al would mention hypertrophy and hyperplasia twice, yet never remark that the findings were erroneous or unproven, if that was the belief of the authors. As is well understood, the teachings of a reference are to be interpreted as one of ordinary skill in the art would interpret them. Thus a fair reading of the disclosures of James et al relating to hyperplasia in asthma, clearly shows that James et al regarded these findings as accurate, the fact that the authors did not chose to expressly assert that they were notwithstanding.

Having asserted the hypothesis that James et al do not believe that hyperplasia occurs in asthmatic lungs, appellant then proceeds to concoct a scenario wherein the rejection applied to the claims is untenable. However, an argument based on a false premise leads to a false conclusion. One of ordinary skill in the art, reading James et al with an unbiased eye would

realize that hyperplasia is the main culprit in the thickening of smooth muscle in the bronchi of asthmatics, as expressly stated therein. The fact that James et al points to a different study that establishes this does not serve to negate this finding, as appellant appears to believe.

Returning to Waksman et al, appellant argues that “airway epithelium and blood vessel endothelium are accordingly two different materials that react differently to radiation. As a result, the intensity of UV radiation to prevent hyperproliferation of vascular smooth muscle cells in response to angioplasty in a blood vessel does not inherently debulk uninjured airway smooth muscle through the epithelium of an airway” (see the instant Brief, the last two sentences on page 30). It is interesting that when discussing the enablement of the instant claims, appellant asserts that the originally filed disclosure, which provides no intensity values whatsoever, is sufficient to enable one of ordinary skill in the art to perform the claimed method without undue experimentation, yet when faced with the teachings of Clarke, which dares to actually provide a starting point for the experimentation, by disclosing an intensity level, the experimentation suddenly becomes undue, and the places required intensity values beyond the reach of one of ordinary skill in the art.

Returning to Waksman et al, appellant argues that the “broad assertion that Waksman teaches irradiating the intima of bronchi is equivalent to irradiate blood vessels is accordingly incorrect” (see the instant Brief, the first sentence on page 31). The examiner must respectfully disagree. The teaching of Waksman et al, as read by one of ordinary skill in the art, clearly show this equivalence, and Waksman et al provide no suggestion or teaching to the contrary, nor has appellant pointed to any. Further, Waksman et al makes no mention of injury when discussing

the treatment of the bronchi. Nor do the instant claims require that the irradiation of injured tissue be avoided.

d. Regarding Claim 50, The References Are Properly Combined And Teach All The Elements Recited In The Claims.

Concerning the teachings of the prior art applied to the claims, appellant argues that the combined references do not teach all the limitations of claim 50. Specifically, appellant asserts that the references to Regunathan et al and Clarke only teach inhibiting hyperplasia of smooth muscle that results from vascular injury. Next appellant notes that vascular smooth muscle is essential for maintaining blood pressure. Concluding, appellant posits that one of ordinary skill in the art “would not apply the methods of Regunathan and/or Clark in a manner that would debulk existing vascular smooth muscle tissue because this would reduce smooth muscle tone” (see the instant Brief, the last sentence on page 31). Here apparently appellant is trying to infer that the term “existing vascular smooth muscle” relates to smooth muscle that has not been produced by hyperplasia, and also appears to be inferring that the debulking would be done throughout the vasculature. However, as before, claim 50 is not so limited. Since clearly Clark and Regunathan do seek to treat existing vascular smooth muscle (the smooth muscle resulting from hyperplasia), and nothing in the references indicates any concern of inhibiting vasoconstriction or vasodilation as a result of this treatment, a similarly localized debulking of smooth muscle in the bronchi would also not be expected to destroy the ability of smooth muscle throughout the entire bronchial tree to be unable to perform the functions it was thought to by

one of ordinary skill in the art to perform at the time of the invention. Continuing, appellant posits that “if the cited reference were combined as set forth in the references, the resulting process would irradiate the airway smooth muscle at a wavelength and intensity that merely prevents future proliferation of smooth muscle cells after an injury” (see the instant Brief, the second sentence on page 32, emphasis in original). However, this conclusion ignores the express teaching of Waksman et al to treat uninjured tissue, as set forth above in section I(a), as well as the teachings of Clark to treat smooth muscle that has already proliferated.

**e. Regarding Claims 33 and 59, One Of Ordinary Skill In The Art
Using The Combined Teachings Of James Et Al, Clarke, Regunatan Et Al
And Waksman Et Al Would Have Employed Radiation That Would Reach
And Affect Mucus Glands.**

Firstly, it is noted that Waksman et al specifically teach using the method discussed therein on the bronchi, a fact admitted by appellant “Waksman teaches that his radionuclide can be used to irradiate the bronchi and the lungs” (see the instant Brief, the fifth sentence of the first full paragraph on page 35). Secondly, the rationale upon which appellant’s assumption of non-obviousness is based – that the smooth muscle performs an essential function, requires that the method produced from the combination entail removing all of the smooth muscle from all of the respiratory (or circulatory) system. However, neither the instant claims, nor the teachings of the prior art applied to the claims are so limited, in that Clarke specifically disclosed that only a portion of the smooth muscle cells be ablated, and as observed by appellant, Clarke shows that

according to the method of Clarke, the thickness of the media is not reduced, (see the instant Brief, the last sentence of the first full paragraph on page 27), that is to say, as a result of the treatment, the thickness of the media is returned to a normal level. This would teach one of ordinary skill in the art that any treatment of the bronchi should, rather than totally obliterate the smooth muscle, as proposed and argued throughout the instant Brief by appellant, instead reduce the thickness thereof, for example the reduction could be to a normal, non-pathological thickness. The conclusion reached by appellant regarding the applied combination “the resulting process would irradiate the airway smooth muscle at a wavelength and intensity that merely prevents the future proliferation of smooth muscle cells after an injury instead of debulking the existing uninjured smooth muscle tissue” (see the instant Brief, the next to last sentence on page 34), is similarly flawed, in that Clarke also teaches “a single wavelength of UV laser radiation can be generated, and such radiation can also be used to ablate the vessel-obstructing plaque or other lesion as well as reduce restenosis. Thus, in this embodiment, UV radiation is transmitted through an optical waveguide to both perform angioplasty and kill smooth muscle cells at the angioplasty site” (see column 3, lines 58-65). Thus clearly Clarke teaches the ablation of “uninjured” blood vessel, i.e. blood vessel narrowed by a pathological process not provoked by surgical invasion – plaque build up, to provide luminal opening which is essentially that which existed prior to the onset of the pathology. The conclusion of appellant is further eroded by the fact that appellant has failed to address the role that the teachings of James et al would play in the conclusion drawn by one of ordinary skill in the art, specifically noting that the smooth muscle thickening observed in asthmatics is primarily caused by hyperplasia.

**e. Regarding Claim 10, The References Are Properly Combined And
Teach All The Elements Recited In The Claims.**

Regarding claims 33 and 59, appellant states that the “cited combination of reference fails to teach anything with respect to debulking mucus gland cells or preventing the mucus gland cells from replicating. However, appellant fails to address the clear teachings of James et al, and what these teachings would have conveyed to one of ordinary skill in the art at the time of the invention. Specifically, James et al specifically identify “mucous gland and goblet cell prominence, and partial occlusion of the lumen with mucus and cellular debris” in the airways of asthmatics (see page 243, the last full sentence). Further, as noted by the examiner, one of ordinary skill in the art, who would at least be a doctor, familiar with pathological processes inducing narrowing of body lumens, and one who is familiar with “treating smooth muscle tissue in the walls of body conduits, and more particularly...treating medical conditions by reducing the bulk of smooth muscle surrounding a body conduit with radiant energy treatment of the smooth muscle” (see the originally filed disclosure, page 1, lines 3-6) would understand that in order to treat such processes, the excess material causing the narrowing of the involved lumen would need to be removed, at least partially, and prevented from manifesting again. Given this, and the ruling that “A person of ordinary skill is also a person of ordinary creativity, not an automaton.” *KSR International Co. v Teleflex Inc.* 82 USPQ2d 1385, 1397 (Supreme Court, 2007), one of ordinary skill in the art would understand that inducing a debulking of mucous gland cells to reduce their prominence, and reduce their output of mucus would be an appropriate treatment for such a condition. Further, regarding claim 59, since the mucus is situated in the

airway “A plurality of mucus glands 54 are positioned around the airway 50 and secrete mucus into the airway.” (see the originally filed disclosure, page 6, lines 4-5), the light must be of sufficient intensity to penetrate the mucus, otherwise it could not affect the smooth muscle beneath. As appellant has not addressed this teaching of James et al as combined with the remaining references, which appellant does actually argue, these arguments are not convincing.

D The Rejection Of Claims 30, 32, 33, 35, 37, 52, 53, 56, 58, And 59 Under 35 U.S.C. 102(b) As Anticipated By Ivanvuta et al

This rejection has been withdrawn.

E Obviousness-Type Double Patenting Rejections

1. Non-Provisional Obviousness-Type Double Patenting Rejection

This rejection has been withdrawn in view of the arguments filled by appellant.

2. Provisional Obviousness-Type Double Patenting Rejections

These rejections are not argued as improper or erroneous by appellant in any way. No allowable subject matter having been claimed, these rejections are deemed proper and have been maintained.

F Summary

The facts and opinions set forth in the Laufer Declaration, while fully considered and carefully weighed in light of the other evidence of record, are insufficient to overcome the examiner's *prima facie* case of obviousness, constructed based solely on the teachings of the prior art and the knowledge of one of ordinary skill in the art at the time the invention was made. This is due to both the fact that Declarant is an interested party in the instant application, and because the factual showings in the form of a communication from the USFDA and an article by one of skill in the art (i.e. the Mitzner et al article referred to in paragraph 8 of the Laufer Declaration, and the opinions of Declarant based thereon are predicated on the proposition that all smooth muscle, or at least the vast majority of smooth muscle to the point where smooth muscle tone is lost throughout the airways of the patient treated by the instantly claimed method is killed, which is not commensurate in scope with the claims at bar. Further, the arguments of appellant, based on the Laufer Declaration are similarly not convincing, and those not based on the Laufer Declaration are not convincing as these do not take into account the ordinary intelligence and creativity which would be possessed and employed by one of ordinary skill in the art, when reading, interpreting, and applying the teachings of the combinations of references applied to the claims.

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

(12) Conclusion

It is the examiner's firm opinion that the appealed claims are not patentable for the reasons argued above. Appellant has presented no convincing argument as to why the rejections set forth above are not obvious or proper. Therefore, it is respectfully submitted that the final rejection be affirmed.

Respectfully submitted,

/david shay/

Primary Examiner, Art Unit 3769

David Shay
April 22, 2011

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